

NOBAMED Paul Danz AG

RUDABLOCK®

REF 080027

Product Description, Intended use, Application

Individually packed, sterile pressure plaster with special wound pad. The wound dressing is protected all around by the carrier material. When the dressing comes into contact with blood, it swells and exerts pressure on the wound.

The special plaster is used to support haemostasis in dialysis and for smaller wounds (e.g. cuts, stab wounds). The size of the plaster is 2.5 cm x 8.5 cm, the carrier material is made of a white non-woven.

Composition

Polyester, viscose, superabsorber, polyacrylate adhesive

Contraindications

The product should not be used in the case of a known allergy against the material.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Legal Requirements

Medical Device according to MDD 93/42/EEC, MDR (EU) 2017/745.

Sterilization of the product complies with DIN EN 11135.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary: paper-paper

packaging

Secondary: folding box made of

cellulose

Tertiary: carton made of

cellulose

Symbols used in labelling

Explanations at www.nobamed.com











Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and ISO 20417.

Storage and Transport

Dry and dustfree, protected from sunlight

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.